UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,796	06/27/2003	Charles J. Doillon	14363	5886

7590 09/22/2005

DOWELL & DOWELL, P.C.
Suite 309
1215 Jefferson Davis Highway
Arlington, VA 22202-3124

EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,796	DOILLON ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-15 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/07/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election without traverse of **Invention I:** corneal implant (claims 1-15 and 25-27), **Polyacrylamide:** Species A (poly (N-alkylacrylamide)), and **Collagen:** Species A (telocollagen or atelocollagen) in the reply filed on June 29, 2005 is acknowledged.

2. Claims 16-24 (non-elected Invention II) and claims 6-7 (non-elected Collagen species) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 29, 2005.

Specification

3. The abstract of the disclosure is objected to because of the following informality: please substitute "ppolymer" (see line 2) with --polymer--. Correction is required. See MPEP § 608.01(b).

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

a. Therefore, the "plurality of membranes" (see claim 15) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 25, "said subject" (see line 3) lacks antecedent basis. Claim 26 depends on claim 25.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4, 5, 8, 10, 13, 14, 25, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perez et al. (WO 94/17851 A1).

Perez et al. disclose a corneal implant comprising a membrane (i.e., film or layer: see Abstract; see page 8, lines 16-18; page 12, lines 34-37), said membrane comprising a biological polymer (e.g. collagen type I, modified forms of collagen, glycosaminoglycans: see Abstract; page 13, lines 18-36; claims 1-5) and a hydrogel (e.g., polyacrylamide: see Abstract; page 11, lines 8-12; claims 1-5). The biological polymer to polyacrylamide ratio is disclosed at page 11, lines 31-32. The membrane thickness is disclosed at page 11, lines 32-34, and page 12, lines 34-37. Said membrane further comprises a chemical crosslink (see Abstract; see entire document). The method as claimed is disclosed in claims 20-22. It should be noted that the intended purpose of the corneal implant of Perez et al. WO 94/17851 A1 is to provide "a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials" (see Abstract; page 7, lines 26-37; page 8, lines 20-24).

9. Claims 1, 4, 5, 10-12, 25, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Graham et al. (US 5,433,745; cited in Applicants' IDS).

Referring to Figures 1-3, Graham et al. disclose a corneal implant comprising a membrane (i.e., film, coat, or layer), said membrane comprising a biological polymer (e.g. coating of a cytophilic component such as collagen, fibronectin, etc: see column 5, lines 11-35; column 10, lines 39-43) and a hydrogel (e.g., polyacrylamide: see column 3, lines 34-59). Said membrane further comprises a chemical crosslink (e.g., 1-(3-dimethylaminopropyl)-3-ethyl carboddimide or EDC: see column 6, lines 46-67; TABLE 3). The method of applying (i.e., implanting) said implant to a patient is disclosed throughout the entire document.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (WO 94/17851 A1) in view of Takezawa et al. (EP 0 387 975 A1).

Perez et al. disclose the invention as claimed in claims 1, 4, 5, 8, 10, 13, 14, 25, and 26 (see 102(b) rejection above). It should be noted that the intended purpose of the corneal implant of Perez et al. WO 94/17851 A1 is to provide "a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials" (see Abstract; page 7, lines 26-37; page 8, lines 20-24).

Although Perez et al. disclose the use of several polymers (e.g., polyacrylamide) suitable for the hydrogel layer, he/she did not particularly disclose using poly(N-isopropylacrylamide) [i.e., PNIPAAM] as the polyacrylamide. However, this is already known in the art. For example, Takezawa et al. disclose a prosthesis (see page 2, lines 17-18) comprising a membrane/film (see page 6, lines 48-49; see claim 9) comprising a collagen-PNIPAAM conjugate (see page 5, page 11, and page 12) in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities (see Abstract; see page 2, lines 3-11; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis comprising a membrane/film comprising a collagen-PNIPAAM conjugate, as taught by Takezawa et al., with the corneal implant of Perez et al., in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities.

12. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al. (US 5,433,745; cited in Applicants' IDS) in view of Takezawa et al. (EP 0 387 975 A1).

Graham et al. disclose the invention as claimed in claims 1, 4, 5, 10-12, 25, and 26 (see 102(b) rejection above). It should be noted that the intended purpose of the corneal implant of Graham et al. US 5,433,745 is to enhance the ability to support epithelial cell growth and/or adhesion (see Abstract; see entire document).

Although Graham et al. disclose the use of several polymers (e.g., polyacrylamide) suitable for the hydrogel layer, he/she did not particularly disclose using poly(N-isopropylacrylamide) [i.e., PNIPAAM] as the polyacrylamide. However, this is already known in the art. For example, Takezawa et al. disclose a prosthesis (see page 2, lines 17-18) comprising a

membrane/film (see page 6, lines 48-49; see claim 9) comprising a collagen-PNIPAAM conjugate (see page 5, page 11, and page 12) in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities (see Abstract; see page 2, lines 3-11; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis comprising a membrane/film comprising a collagen-PNIPAAM conjugate, as taught by Takezawa et al., with the corneal implant of Graham et al., in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities.

13. Claims 9, 15, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (WO 94/17851 A1).

Perez et al. disclose the invention as claimed in claims 1, 4, 5, 8, 10, 13, 14, 25, and 26 (see 102(b) rejection above). Perez et al. did not particularly disclose the claimed ratio of 0.3:1.0 (w/w) biological polymer to polyacrylamide. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the corneal implant of Perez et al. with a particular/specific (w/w) ratio of biological polymer to polyacrylamide since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, intraocular and/or corneal implants comprising a plurality of membranes (i.e., layers, films, laminates, etc.) are well known in the art and would have been obvious in view of a patient's condition/disease, with the ordinary practitioner having been left

to select a particular number of membranes based on the intended purpose (e.g., different layers may provide (i) different refractive properties; (ii) site for epithelial cell adhesion/attachment; (iii) modifying the curvature of the cornea; etc.).

Regarding claim 27, packages/kits of intraocular and/or corneal implants are inherent and well known in the art. A mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). In re Gulack, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").

14. Claims 8, 9, 13-15, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al. (US 5,433,745; cited in Applicants' IDS).

Graham et al. disclose the invention as claimed in claims 1, 4, 5, 10-12, 25, and 26 (see 102(b) rejection above). Graham et al. did not particularly disclose the claimed ratio of 0.3:1.0 (w/w) biological polymer to polyacrylamide, or, the claimed membrane thickness of about 20 microns to about 400 microns. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the corneal implant of Graham et al. with a particular/specific (w/w) ratio of biological polymer to polyacrylamide, or, a particular membrane thickness, since it has been held that where the general conditions of a

claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, intraocular and/or corneal implants comprising a plurality of membranes (i.e., layers, films, laminates, etc.) are well known in the art and would have been obvious in view of a patient's condition/disease, with the ordinary practitioner having been left to select a particular number of membranes based on the intended purpose (e.g., different layers may provide (i) different refractive properties; (ii) site for epithelial cell adhesion/attachment; (iii) modifying the curvature of the cornea; etc.).

Regarding claim 27, packages/kits of intraocular and/or corneal implants are inherent and well known in the art. A mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). In re Gulack, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Yoshioka et al. (US 6,897,064 B2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 17, 2005

David H. Willse
Primary Examiner